



## **DEPARTMENT OF HOMELAND SECURITY**

### **U.S. Customs and Border Protection**

#### **Notice of Issuance of Final Determination Concerning Subdermal Needle Electrodes**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** Notice of final determination.

**SUMMARY:** This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of Rhythmink International, LLC’s Subdermal Needle Electrode. Based upon the facts presented, CBP has concluded that the country of origin of the Subdermal Needle Electrode is the United States or Japan, depending on the country of origin of the needle electrode used in the assembly of the Subdermal Needle Electrode, for purposes of U.S. Government procurement.

**DATES:** The final determination was issued on July 13, 2018. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination no later than [INSERT 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** James Kim, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade (202) 325-0158.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on July 13, 2018, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR Part 177, subpart B), CBP issued a final determination concerning the country of origin of Rhythmink International, LLC’s Subdermal Needle Electrode, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H296072, was issued under procedures set forth at 19 CFR Part 177, subpart B, which

implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511-18). In the final determination, CBP concluded that the assembly and processing in China does not result in a substantial transformation. Therefore, the country of origin of RhythmLink International, LLC's Subdermal Needle Electrode is the United States or Japan, depending on the country of origin of the needle electrode used in the assembly of the Subdermal Needle Electrode, for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the *Federal Register* within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the *Federal Register*.

Dated: July 13, 2018.

**Alice A. Kipel,**

*Executive Director,*

*Regulations and Rulings,*

*Office of Trade.*

**HQ H296072**

**July 13, 2018**

**OT:RR:CTF:VS** H296072 JK

**CATEGORY:** Origin

David S. Robinson  
Nexsen Pruet, PLLC  
4141 Parklake Avenue  
Suite 200  
Raleigh, NC 27612

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Subdermal Needle Electrode; Substantial Transformation

Dear Mr. Robinson:

This is in response to your correspondence of March 29, 2018, requesting a final determination on behalf of Rhythmink International, LLC (“Rhythmink”), pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. § 177.21 *et seq.*).

This final determination concerns the country of origin of the Subdermal Needle Electrode. We note that Rhythmink is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

**FACTS:**

Rhythmink is headquartered in Columbia, North Carolina and manufactures and distributes medical devices and provides custom packaging, private labeling, custom products, and contract manufacturing to its customers.

The subject merchandise is a Subdermal Needle Electrode (“Product”), a high-tensile strength stainless steel wire cleared by the U.S. Food & Drug Administration (“FDA”) for performing both stimulating and recording electrical conductor functions. The Product serves as a physical connection between a patient and medical diagnostic equipment that records and/or elicits neurophysical biopotentials. The FDA classifies and designates the Product as a “needle electrode,” defined in FDA regulations as “a device which is placed subcutaneously to stimulate or to record electrical signals.” *See* 21 C.F.R. § 882.1350.

Rhythmink’s fully assembled, packaged Product consists of the following six component parts: the needle electrode, the leadwire, a miniscule amount of solder, a heat shrink tube, a protective cover for the needle, and packaging. Rhythmink sells the Product in varying lengths

and styles, and end users can customize the color of the connecting leadwire. The leadwire acts as an electrical conductor that transfers low voltage electrical signals from the needle electrode to medical diagnostic equipment. You state that the functionality of the Product is common to all lengths and is unchanged by the color of the pre-connected leadwire. You also state that other varieties of needle electrodes are available in the market that are not pre-connected to a leadwire. Such needle electrodes may connect to a leadwire without soldering by using alligator clips and other removable connectors. Other varieties of needle electrodes may utilize wireless transmission, eliminating the need for a leadwire altogether.

You state that RhythmLink conducts all of the engineering and design of the Product in the United States. The engineering and design of the Subdermal Needle Electrode include the following steps: research and development; design control; IP generation; regulatory clearances; specifications; engineering drawings; work instructions; tooling, fixtures, and equipment designs; functional verification testing; sterilization validation; packaging, sterile barrier and shelf life validation; and process validations.

RhythmLink outsources the actual manufacturing and production of the FDA-compliant needle electrodes (prior to being attached to other components) to a contract manufacturer of medical devices. The contract manufacturer manufactures the needle electrode entirely in either the United States or Japan using either U.S. or Japanese stainless steel material. You state that its production processes are largely proprietary and that the manufacturing costs are unknown. Under the manufacturing process of the needle electrode, a stainless steel wire is cut to precise lengths, and the cut wire undergoes precise facet grinding, passivation, and electropolishing. The needle electrode is manufactured to RhythmLink's precise specifications, with three facets ground onto the front end to meet sharpness and insertion force requirements. Finally, it is packaged and shipped. The country of origin of the needle electrode is marked as either the United States or Japan, depending on the country in which it was manufactured.

The Korean-origin leadwire is a commercially available 26-gauge twisted copper wire comprising 19 strands of 38-gauge copper wire with medical grade PVC covering. The leadwire is available in a total of 35 color options. The Korean supplier of this wire cuts the wire, crimps a socket pin, attaches a connector to one end of the wire, and ships the wire to China.

The needle electrodes from the United States or Japan are exported to China for additional assembly and processing. The 'naked' end of the Korean leadwire is soldered to the needle electrode using Chinese-origin solder, which is a mix of tin and copper and represents a quarter of a percent of the Product's cost. You state that the soldering process takes roughly a second, substantiated by a video you provided of the process, and that six operators can professionally solder 30,000 Products in a day. The soldered Product undergoes ultrasonic cleaning and drying (spin and convention drying) in bulk. A Japanese-origin heat shrink tube, available in almost 40 different diameters, is added to protect the solder joint. A U.S.-origin protective needle cover is placed over the needle electrode to prevent accidents. Finally, the product is packaged in a Tyvek pouch and cardboard packaging of Chinese-origin and re-exported to the United States.

In the United States, the Product is subject to sterilization and a randomized sampling and testing protocol prior to sale.

You provided a catalog of RhythmLink's products, which includes the Subdermal Needle Electrode. You also provided a detailed process map depicting the various processing steps involved in the engineering, manufacture, and sale of the Product, along with information on the country in which each step occurs and the skill and technology level required for each step. In addition, you provided component specifications for the Product.

## **ISSUE:**

What is the country of origin of the Subdermal Needle Electrode for purposes of U.S. Government procurement?

## **LAW AND ANALYSIS:**

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*) ("TAA").

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

*See also* 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define "U.S.-made end product" as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. See *United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

Courts have held that when the properties and uses of a product are predetermined by the material from which it was made, no substantial transformation occurs. For example, in *Superior Wire v. United States*, 669 F. Supp. 472 (Ct. Int'l Trade 1987), *aff'd*, 867 F.2d 1409 (Fed. Cir. 1989), wire rod in coils was shipped to Canada where it was drawn into wire. The tensile strength of the final product was increased by approximately 30 to 40 percent as the rod was reduced in cross-sectional area by about 30 percent and was elongated. The court determined that the drawing operation did not result in a substantial transformation, pointing out that the properties of the wire rod and its uses were determined by the chemical content of the rod and the cooling processes used in its manufacture, and that the wire rod dictated the final form of the finished wire.

For purposes of this ruling, we assume that the country of origin of the stainless steel wire used to manufacture the needle electrode is the United States or Japan. You assert that the assembly and processing that occurs in China, a non-designated country, does not substantially transform the U.S. or Japanese-origin needle electrode, claimed to be the essential character of the Product, into a new and different article of commerce.

In HQ 555774, dated December 10, 1990, Customs, a predecessor of CBP, ruled that Japanese-origin wire cut to varying length and electrical connectors crimped onto the ends of the wire in the United States did not constitute substantial transformation. Customs found that the essential character and use of the wire before and after the processing was the same, *i.e.*, to conduct electrical current.

In HQ H248851, dated July 8, 2014, CBP held that an Israeli-origin CO2 tube was not substantially transformed in China when cut to length and attached to four other components from Israel and China. CBP found that the CO2 tube performed the essential function of the finished product, which was the delivery of breath for monitoring the CO2 level in a patient's breath. By way of the assembly process in China, the CO2 tube was attached to other components that facilitated its function and did not lose its individual identity in the process.

Like the operations described in HQ 555774 and HQ H248851, the assembly and processing that occur in China are simple and minor processes that leave the identity of the needle electrode intact. The soldering of the leadwire to the needle electrode occurs in roughly one second. The remaining processing of the Product, consisting of cleaning and drying, adding a heat shrink and protective cover, and packaging, are likewise simple and minor operations involving highly repetitive, low-skill functions.

As in *Superior Wire*, the properties and uses of the Product are predetermined by the qualities of the needle electrode itself, which do not change as a result of the Chinese assembly and processing operations. The Product's main function is to penetrate the skin or other membrane to allow medical diagnostic equipment to record or stimulate neurophysical biopotentials. While the presence of a pre-connected leadwire does provide convenience for the end user, by eliminating the need to use removable connectors for attaching a leadwire, the needle electrode is nonetheless capable of performing its main function without a pre-connected leadwire. Prior to any Chinese assembly or processing, the needle electrode already meets the definition of the FDA regulated "needle electrode." As in HQ H248851, the attachment of the leadwire and other components to the needle electrode may facilitate its function, but the needle electrode does not lose its individual identity in the process. As a result, we find that the U.S. or Japanese-origin needle electrode, rather than the Korean-origin leadwire, determines the essential character of the Product.

We find that the name, character, and use of the needle electrode remain unchanged after the attachment of the leadwire and other components. Accordingly, we find that the needle electrode is not substantially transformed as a result of the Chinese assembly and processing operations.

**HOLDING:**

The country of origin of the Subdermal Needle Electrode for U.S. Government procurement purposes is the United States or Japan, depending on the country of origin of the needle electrode.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel  
Executive Director  
Regulations and Rulings  
Office of Trade